

CLAIMS:

1. A pharmaceutical composition comprising a propylene glycol solvate of an API.
2. The composition according to claim 1, wherein:
 - (a) the mole ratio of propylene glycol to API in the solvate is in the range of 0.25 to 2;
 - (b) the solvate is in a crystalline form;
 - (c) the composition further comprises a powder X-ray diffraction spectrum which differs from the corresponding powder X-ray diffraction spectrum of the unsolvated API by at least one property selected from the group consisting of: a loss of at least one peak, shifting of more than half the peaks at the 2-theta angle by at least 0.3 degrees, and formation of at least one new peak;
 - (d) the solvate is stable to temperatures of up to 50 degrees C under a stream of gas in a thermogravimetric analysis apparatus;
 - (e) the API is in the form of a metal salt;
 - (f) the metal is an alkali metal or an alkaline earth metal;
 - (g) the metal is selected from Na, K, Li, Ca and Mg;
 - (h) the API is selected from an API of Table 3;
 - (i) the API has low aqueous solubility and is selected from the group consisting of steroid drugs;
 - (j) the composition further comprises a pharmaceutically-acceptable diluent, excipient or carrier;
 - (k) the API is olanzapine and the composition is characterized by a PXRD pattern comprising peaks expressed in terms of 2-theta angles, wherein:
 - (i) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 8.33, 15.61, and 21.41 degrees;

- (ii) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 8.95, 14.47, 22.03, and 23.29 degrees;
 - (iii) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 14.47, 17.95, 19.57, and 20.65 degrees; or
 - (iv) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 8.33, 8.95, 14.47, 15.61, 17.95, and 23.29 degrees; or
 - (v) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 14.47, 15.61, and 20.65 degrees;
 - (vi) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 8.33 and 21.41 degrees;
 - (vii) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises a peak at 14.47 degrees;
 - (viii) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 14.47 and 22.03 degrees;
 - (ix) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises peaks at 17.95 and 20.65 degrees; or
 - (x) said form is a propylene glycol solvate of olanzapine and said PXRD pattern comprises a peak at 8.33 degrees;
- (l) the API is cortisone acetate and the composition is characterized by a PXRD pattern comprising peaks expressed in terms of 2-theta angles, wherein:

- (i) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises peaks at 10.71, 14.54, and 18.49 degrees;
- (ii) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises peaks at 5.31, 15.66, 21.33, and 23.49 degrees;
- (iii) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises peaks at 5.31, 10.71, 14.54, 15.66, 18.49, 21.33, and 23.49 degrees;
- (iv) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises peaks at 14.54 and 18.49 degrees;
- (v) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises peaks at 15.66 and 21.33 degrees;
- (vi) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises a peak at 5.31 degrees;
- or
- (vii) said form is a propylene glycol solvate of cortisone acetate and said PXRD pattern comprises a peak at 18.49; or
- (m) the API is naproxen sodium salt and the composition is characterized by a PXRD pattern comprising peaks expressed in terms of 2-theta angles, wherein:
 - (i) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises peaks at 6.67, 18.55, and 22.79 degrees;
 - (ii) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises peaks at 9.65, 15.77, and 20.83 degrees;

- (iii) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises peaks at 6.67 and 18.55 degrees;
- (iv) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises a peak at 9.65 degrees;
- (v) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises a peak at 6.67 degrees;
- (vi) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises peaks at 15.77, 18.55, and 27.17 degrees; or
- (vii) said form is a propylene glycol solvate of naproxen sodium salt and said PXRD pattern comprises peaks at 9.65 and 22.79 degrees.

3. A method for preparing a propylene glycol solvate of an API, which method comprises:

- (a) contacting propylene glycol with an API in solution;
- (b) crystallizing a propylene glycol solvate of the API from the solution; and
- (c) isolating the solvate.

4. The method according to claim 3, wherein:

- (a) the step of crystallizing the solvate comprises changing the pH of the solution to precipitate the solvate;
- (b) the pH is raised to render the solution alkaline;
- (c) the step of isolating the solvate includes separating the solution phase from the solvate;
- (d) crystalline solvate is dried to remove excess solution phase;

- (e) the composition further comprises a powder X-ray diffraction spectrum which differs from the corresponding powder X-ray diffraction spectrum of the unsolvated API by at least one property selected from the group consisting of: a loss of at least one peak, shifting of more than half the peaks at the 2-theta angle by at least 0.3 degrees, and formation of at least one new peak;
- (f) the solvate is stable to temperatures of up to 50 degrees C under a stream of gas in a thermogravimetric analysis apparatus;
- (g) the API is in the form of a metal salt;
- (h) the metal is an alkali metal or an alkaline earth metal;
- (i) the metal is selected from Na, K, Li, Ca and Mg;
- (j) the API is selected from an API of Table 3;
- (k) the API has low aqueous solubility and is selected from the group consisting of steroid drugs;
- (l) the API is olanzapine; or
- (m) the API is cortisone acetate.

5. A method for decreasing the hygroscopicity of an API, which method comprises

- (a) contacting the API with propylene glycol in solution;
- (b) crystallizing a propylene glycol solvate of the API from the solution; and
- (c) isolating the solvate, wherein the solvate has decreased hygroscopicity as compared to the API.

6. A method for increasing the aqueous solubility of an API, which method comprises

- (a) contacting the API with propylene glycol in solution;
- (b) crystallizing a propylene glycol solvate of the API from the solution; and
- (c) isolating the solvate, wherein the solvate has increased aqueous solubility as compared to the API.